

## **REMARKS**

Reconsideration of the above-identified application in view of the preceding amendments and following remarks is respectfully requested.

Claims 25-32 remain pending in this application. Claims 1-12, 16 and 33 have been cancelled without prejudice to expedite prosecution. Applicants reserve the right to prosecute these cancelled claims in a later filed co-pending application. Claims 13-15 and 17-24 have been withdrawn from consideration. Claim 25 has been amended herein to more particularly point out and define the patentable features of the subject invention. No new matter has been added by these amendments as support therefor is found throughout the specification and drawings of the subject application.

### **Claim Rejections Under 35 U.S.C. §102(b)**

Claims 1-12 were rejected under 35 U.S.C. §102(b) in view of U.S. Patent No. 3,540,451 to Zeman. Claims 1-12 have been cancelled without prejudice to expedite prosecution, thus obviating this rejection, and withdrawal thereof is respectfully requested.

Claims 1, 2, 9 and 10 were rejected under 35 U.S.C. §102(b) in view of U.S. Patent No. 4,318,401 to Zimmerman. Claims 1, 2, 9 and 10 have been cancelled without prejudice to expedite, thus obviating this rejection, and withdrawal thereof is respectfully requested.

### **Claim Rejections Under 35 U.S.C. §103(a)**

Claims 3-8, 11, 12 and 25-32 were rejected under 35 U.S.C. §103(a) over U.S. Patent No. 4,318,401 to Zimmerman in view of U.S. Patent No. 3,540,451 to Zeman. Claims 3-8, 11 and 12 have been cancelled without prejudice, thus obviating this rejection with respect to those claims.

As for the remaining claims, it is respectfully submitted that neither Zeman nor Zimmermann disclose or suggest the invention defined by amended Claim 25, either alone or in combination, in whole or in part.

Zimmermann discloses a vascular access portal that includes, among other things, a cannula 14 having a passage 20 and an obturator 22. The cannula 14 has a distal end surface 30 forming an acute angle with respect to the main axis of the cannula. The obturator 22 fits within the passage 20 of cannula 14, whereby the distal end surfaces 38 and 40 of obturator 22 form "an acute angle with respect to the main axis of the obturator for matching the angularity of the cannula distal end." (Col. 5, lns. 6-9; and see Fig. 2). In use, the distal end surface 30 of the cannula 14 is configured for "resting against the outer blood vessel wall 27," (col. 3, ln. 10), just as the distal end surfaces 38, 40 of obturator 22 "contact vessel wall 27" (col. 3, ln. 18). Thus, Zimmerman fails to disclose or suggest a vascular access portal wherein the distal end portions of cannula 14 and obturator 22 are disposed within a blood vessel. Zimmermann also fails to disclose or suggest a vascular access port where the distal end surfaces of the cannula and obturator are perpendicular to the main axis of the access port.

Zeman discloses a drainage cannula for the abdominal cavity. Referring to Fig. 2, the drainage cannula includes a threaded hollow stem 11 with a distal flange 11a that acts as a stop for anchor plate 12, which is secured against the interior of the abdominal musculature 16. The cannula is closed by a sealing pin 24, which is inserted and threaded into the stem 11 by way of thread 27. There is nothing in the drawings or specification of the Zeman patent that discloses or suggests that the hollow stem 11 and the sealing pin 24 are of equal length. Moreover, nothing in Zeman discloses or suggests that the distal end

surface of the sealing pin will be coplanar with the distal end surface of the stem when the sealing pin is inserted and threaded into the stem.

Furthermore, the drawings referenced and measured by the Examiner in the Office Action have been measured by applicant representative, using a standard metric ruler, and contrary to the Examiner's assertion, it is submitted that, the sealing pin 24 shown in Fig. 2 is at least 2 mm longer than the hollow stem 11. That is, the axial length of the pin 24, excluding the knurled handle is 49 mm, whereas the axial length of the threaded stem 11 is 47 mm. Still further and even more importantly, the distal end surface of the threaded stem 11 is not shown to extend perpendicular to the main axis of the stem. Rather, the distal end surface of the stem is shown to be at an angle to the main axis of the stem. This is indicative of the fact that the stem 11 is threaded. Indeed, using a standard protractor, the distal surface of the threaded stem 11 has been measured by applicant's representative to be drawn at a 5° angle relative to the longitudinal axis of stem 11. Thus, Zeman fails to disclose or suggest an access port where the distal end surfaces of the port and sealing pin are either coplanar or perpendicular to the main axis of the access port.

It is respectfully submitted that neither Zimmerman nor Zeman disclose or suggest, either alone or in combination, in whole or in part, the invention set forth in amended Claim 25 of the subject application. More particularly, neither reference discloses or suggests an apparatus for facilitating vascular access which includes, among other things, a vascular access port defining an elongated tubular body of predetermined length with a central lumen bounded by a continuous, uninterrupted outer wall, the tubular body having a longitudinal axis, and opposed proximal and distal end portions, the distal end portion of the tubular body adapted and configured for introduction into a

blood vessel and defining a flat annular distal end surface extending perpendicular to the longitudinal axis of the central lumen, as well as an elongated cylindrical plug body dimensioned and configured for insertion into the central lumen of the vascular access port, the plug body having a length that is substantially equal to the length of the vascular access port, a longitudinal axis, and a flat circular distal end surface extending perpendicular to the longitudinal axis of the plug body, whereby the flat circular distal end surface of the plug body prevents blood flow into the lumen of the access port when the distal end portion of the access port is disposed within the blood vessel, the plug body is engaged within the lumen of the access port and the flat annular distal end surface of the access port is coplanar with the flat circular distal end surface of the plug body, as well as a locking mechanism associated with the proximal end portion of the elongated cylindrical plug body for releasably coupling the plug body to the vascular access port.

Furthermore, a person skilled in the art of designing vascular access devices, endeavoring to construct a new and useful device configured to extend into a blood vessel to provide access thereto, with a plug dimensioned to prevent blood from entering the access port, would not have looked to a patent covering an abdominal drainage device, such as the Zeman reference, for a teaching, since blood clotting is not an issue within the abdominal cavity.

For each of the forgoing reasons, it is respectfully submitted that amended Claim 25 and each of the claims depending therefrom, are not rendered obvious by the combination of Zimmermann and Zeman. Withdrawal of the rejection under 35 U.S.C. §103(a) is therefore respectfully requested.

Claims 1-3, 5, 6, 8-12, 25, 26 and 28-32 were rejected under 35 U.S.C. §103(a) over U.S. Patent No. 3,572,333 to Hubert in view of U.S. Patent No. 4,318,401 to

Zimmerman. Claims 1-3, 5, 6, and 8-12 have been cancelled without prejudice, thus obviating this rejection with respect to those claims.

As for the remaining claims, it is respectfully submitted that neither Hubert nor Zimmermann disclose or suggest the invention defined by amended Claim 25, either alone or in combination, in whole or in part.

According to the Examiner, "Hubert fails to disclose the access port having an elongated tubular body defining a flat annular distal end surface, and a plug having a flat distal end surface, so that the flat annular end surface of the access port is coplanar with the flat circular distal end surface of the plug when the plug is inserted into the access port." (Office Action, page 6).

As noted above, Zimmermann discloses an access port with a cannula and obturator that have distal end surfaces with matching acute angularity with respect to the main axis of the access port.

Therefore, it is respectfully submitted that neither Hubert nor Zimmerman disclose or suggest, either alone or in combination, in whole or in part, the invention defined by amended Claim 25 of the subject application. More particularly, neither reference discloses or suggests an apparatus for facilitating vascular access which includes, among other things, a vascular access port defining an elongated tubular body of predetermined length with a central lumen bounded by a continuous, uninterrupted outer wall, the tubular body having a longitudinal axis with opposed proximal and distal end portions, the distal end portion adapted and configured for introduction into a blood vessel and defining a flat annular distal end surface extending perpendicular to the longitudinal axis of the central lumen, as well as an elongated cylindrical plug body dimensioned and configured for insertion into the central lumen of the vascular access

port, the plug body having a length that is substantially equal to the length of the vascular access port and a flat circular distal end surface extending perpendicular to the longitudinal axis of the plug body, whereby the flat circular distal end surface of the plug body prevents blood flow into the lumen of the access port when the distal end portion of the access port is disposed within the blood vessel, the plug body is engaged within the lumen of the access port and the flat annular distal end surface of the access port is coplanar with the flat circular distal end surface of the plug body, as well as a locking mechanism associated with the proximal end of the elongated cylindrical plug body for releasably coupling the plug body to the vascular access port.

For each of the forgoing reasons, it is respectfully submitted that amended Claim 25 and each of the claims depending therefrom, are not rendered obvious by the combination of Hubert and Zimmermann. Withdrawal of the rejection under 35 U.S.C. §103(a) is therefore respectfully requested.

Claims 4, 7 and 27 were rejected under 35 U.S.C. §103(a) over U.S. Patent No. 3,572,333 to Hubert in view of U.S. Patent No. 4,318,401 to Zimmerman.

Claims 4 and 7 have been cancelled without prejudice, thus obviating this rejection with respect to those claims. Claim 27, however, depends from amended Claim 25 and thus includes all of the limitations set forth therein. As noted above, Claim 25 is believed to be patentable over the combination of Hubert and Zimmermann. Therefore, for each of the reasons stated above with respect to the rejection of Claim 25 based on the combination of Hubert and Zimmermann, Claim 27 is also not rendered obvious.

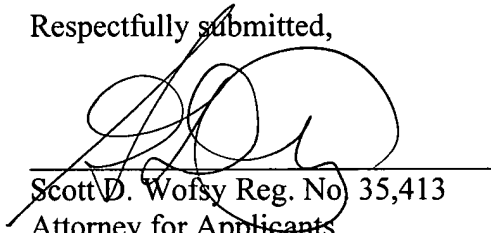
### Conclusion

It is respectfully submitted that each of the remaining claims of the subject application, namely Claims 25-32, are in condition for allowance, and such action is earnestly solicited.

If after reviewing this amendment, the Examiner believes that a telephone or personal interview would facilitate the resolution of any remaining matters the undersigned attorney may be contacted at the number set forth hereinbelow.

Respectfully submitted,

Date: March 19, 2004



\_\_\_\_\_  
Scott D. Wofsy Reg. No. 35,413  
Attorney for Applicants  
EDWARDS & ANGELL, LLP  
P.O. Box 9169  
Boston, MA 02209  
Telephone: (203) 353-6831  
Customer No. 21874